

Remarks/Arguments:

With the present amendment, claims 2, 3, 9-11, and 18-24 are pending. New claims 22-24 have been added. No new matter has been added.

Specification Objections

The Specification has been objected for having the phrase "inner wall 1i" but element "1i" was not present in the drawings. FIG. 12 has been amended to include the reference numeral "1i". Applicants respectfully request the objection to the Specification be withdrawn.

Claim Objections

Claim 2 was objected to for citing "a said stop means." Claim 2 has been amended to remove the word "said." Applicants respectfully request the objection to the Claims be withdrawn.

Claim rejections

Claim rejections under 35 U.S.C. §112

Claims 2, 3, 9-11, and 21 stand rejected under 35 U.S.C. §112 as indefinite for reciting the term "needles" without proper antecedent basis. Claims 2, 3, 9-11, and 21 have been amended to provide proper antecedent basis. Applicants respectfully request the rejection be withdrawn.

Claim rejections under 35 U.S.C. §102

Claim 18 stands rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,971,953 to Bachynsky (Bachynsky").

Amended claim 18 recites, *inter alia*, a device for needle biopsy *adapted for aspiration of tissue specimens* with a syringe cylinder, with a plunger displaceable therein as well as with a needle means. The needle means has at least one needle, whose channel opens into the interior of the cylinder. A *ventilation means* is formed by at least one overflow channel, which is formed at a distance from the syringe bottom in the inner wall of the cylinder. The length of the channel in the direction of the cylinder axis makes it possible that the volume between the bottom and the plunger can be temporarily connected with the interior of the cylinder that is located above the plunger via at least one overflow channel.

In order to anticipate a claim under 35 U.S.C. §102, the reference must teach every element of the claim. M.P.E.P. §2131. Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) and M.P.E.P. §2131.

The present claim contains "means for" language that is to be construed under 35 U.S.C. §112, sixth paragraph. In such a case, the USPTO must give claims their broadest reasonable interpretation in light of and consistent with the written description in the application. See *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994).

The "ventilation means" recited in claim 18 is disclosed in the present specification on page 12, lines 4-18, and FIG. 12. The ventilation means provides for fluid communication between tissue material, located in the at least one needle and/or syringe cylinder 1 between bottom 5 and plunger 2 during tissue aspiration, and atmosphere, which enters cylinder 1 through a top end along shaft 3 of plunger 2. Overflow channels 37 provide the ventilation of atmosphere into the space between bottom 5 and plunger 2 when the head of plunger 2 is disposed between ends of the ventilation channels 37.

Bachynsky, on the other hand, discloses a dual chamber syringe for administering a medication. Bachynsky discloses a flow channel 30 that allows liquid diluent 23 trapped between two pistons 32, 33 to flow out and mix with a dry drug 24. Bachynsky in no way contemplates or desires ventilation provided by the ventilation means recited in claim 18. Because Bachynsky is a drug delivery syringe, the potential for adding air into either the liquid diluent 23 or the dry drug 24 could be harmful or even fatal to the subject, Bachynsky most certainly does not disclose or suggest the ventilation means claimed in claim 18.

Further, claim 18 has been amended to recite in the preamble that the claimed device is "adapted for aspiration of tissue specimens." The Office Action, page 3, paragraph 7, incorrectly states that Bachynsky discloses a device for needle biopsy.

M.P.E.P. §2111.02 recites that "[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

The preamble in claim 18 has been amended to further define the claimed invention as being *adapted for the aspiration of tissue specimens*. While the amended language is arguably functional language, such functional language must be construed as a limitation that must be considered when considering the patentability of the claim. Regarding a functional limitation, the M.P.E.P. states:

A functional limitation *must be evaluated and considered*, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient, or step. . . . limitations such as "members *adapted to be positioned*" . . . serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976)

M.P.E.P. § 2173.05(g) (emphasis added).

Because the claimed invention is adapted for the aspiration of tissue specimens, such functional limitation must be addressed when determining the patentability of the claimed invention. As discussed above, Bachynsky's device is used to deliver medication. Bachynsky's device *cannot* be used for aspiration of tissue specimens. Bachynsky discloses a syringe having a lower piston 32 that is coupled to a tubular member 36. Tubular member 36 is slidably disposed within plunger bore 41 of plunger 40. Assuming, *arguendo*, that one would attempt to aspirate with Bachynsky's device, withdrawal of plunger 40 from syringe bore 13 would allow plunger 40 to translate along tubular member 36, leaving tubular member 36 and its associated piston 32 in syringe bore 13.

Because Bachynsky fails to disclose or suggest all of the limitation of claim 18, Applicants respectfully submit that the rejection of claim 18 is improper. Applicants respectfully request reconsideration and allowance of claim 18.

Claim rejections under 35 U.S.C. §103

Claim 19 stands rejected under 35 U.S.C. §103 as unpatentable over Bachynsky in view of U.S. Patent No. 6,482,187 to Gibbs ("Gibbs"). Claim 19 depends from claim 18. Gibbs is cited for allegedly disclosing an injection device comprising a plurality of needles. Gibbs fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Gibbs fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination

of Gibbs and Bachynsky fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness.

Claim 21 stands rejected under 35 U.S.C. §103 as unpatentable over Bachynsky in view of Gibbs and U.S. Patent No. 3,552,394 to Horn ("Horn"). Claim 21 depends from claim 18. Horn is cited for allegedly disclosing a syringe device having a plurality of needles. The proposed combination of Bachynsky with Gibbs and Horn fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Horn fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Horn with Bachynsky and Gibbs fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness.

Claim 20 stands rejected under 35 U.S.C. §103 as unpatentable over Bachynsky in view of U.S. Patent No. 6,972,006 and U.S. Patent Application Publication No. US2004/0054332, both to Ferguson ("Ferguson"). Claim 20 depends from claim 18. Ferguson is cited for allegedly disclosing at least one indicator projection that projects from the inner wall of the cylinder. The proposed combination of Bachynsky with Ferguson fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Ferguson fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Bachynsky with Ferguson fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness.

Claims 2 and 3 stand rejected under 35 U.S.C. §103 as unpatentable over Bachynsky in view of Gibbs and U.S. Patent No. 6,290,683 to Erez et al. ("Erez"). Claims 2 and 3 ultimately depend from claim 18. Erez is cited for allegedly disclosing a device with a stop means that limits the depth of penetration of the needle into the body. The proposed combination of Bachynsky with Gibbs and Erez fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Erez fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Bachynsky with Gibbs and Erez fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness.

Claim 9 stands rejected under 35 U.S.C. §103 as unpatentable over Bachynsky in view of Gibbs and U.S. Patent No. 2,551,902 to Rieck ("Rieck"). Claim 9 depends from claim 18. Rieck is cited for allegedly disclosing a device comprising a common projection sleeve that can

be attached by plugging to the syringe cylinder over the needles. The proposed combination of Bachynsky with Gibbs and Rieck fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Rieck fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Bachynsky with Gibbs and Rieck fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness.

Claims 10 and 11 stand rejected under 35 U.S.C. §103 as unpatentable over Bachynsky in view of Gibbs and U.S. Patent No. 3,757,780 to Ishikawa ("Ishikawa"). Claims 10 and 11 ultimately depend from claim 18. Ishikawa is cited for allegedly disclosing a device with a filter means that is arranged in a path between the opening of channels into the tips of the needles and the interior of the syringe cylinder. The proposed combination of Bachynsky with Gibbs and Ishikawa fails to make up the deficiencies of Bachynsky with respect to claim 18. Namely, Ishikawa fails to disclose or suggest the limitation of the claimed ventilation means. Because the proposed combination of Bachynsky with Gibbs and Ishikawa fails to disclose the claimed invention, Applicants respectfully submit that the proposed combination fails to provide a *prima facie* case of obviousness.

New claims 22-24

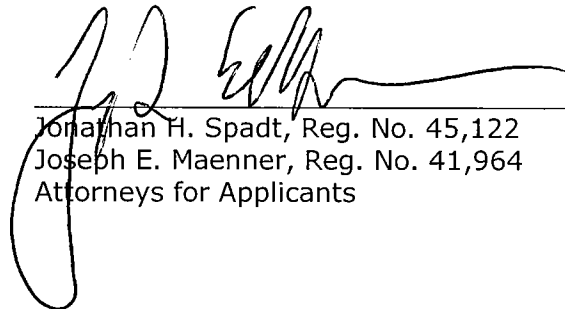
New claims 22-24 have been added, with claim 22 being independent and claims 23 and 24 each depending from claim 22. Claim 22 recites, *inter alia*, a device for needle biopsy for aspirating tissue specimens. The device for needle biopsy comprises a cylinder having an inner wall and an outer wall. The inner wall has a ventilation cutout formed therein. The device for needle biopsy further comprises a needle means having at least one needle whose channel opens into the interior of the cylinder. A plunger has a single piston with a solid face. The plunger is disposed in the cylinder and is adapted for reciprocal translation within the cylinder such that, when the plunger is withdrawn from the cylinder, tissue is aspirated into the at least one needle and/or the cylinder.

The cited prior art fails to disclose or suggest at least the limitation of the plunger being disposed in the cylinder and being adapted for reciprocal translation within the cylinder such that, when the plunger is withdrawn from the cylinder, tissue is aspirated into the needle and/or the cylinder.

Conclusion

In light of the above amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Applicants respectfully request prompt consideration and allowance of the claims.

Respectfully submitted,



Jonathan H. Spadt, Reg. No. 45,122
Joseph E. Maenner, Reg. No. 41,964
Attorneys for Applicants

JHS/JEM/

Enclosure: Replacement Sheet containing amended Figure 12
CLEAN COPY OF AMENDED ABSTRACT

Dated: April 10, 2008

P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.